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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IN RE: DA VINCI SURGICAL ROBOT ANTITRUST LITIGATION	Lead Case No. 3:21-cv-03825-VC **DEFENDANT AND COUNTERCLAIMANT INTUITIVE SURGICAL, INC.'s MOTION TO EXCLUDE TESTIMONY OF DR. T. KIM PARNELL** Hearing Date: June 8, 2023 Hearing Time: 1:00 PM Hearing Place: Courtroom 4 Judge: Hon. Vince Chhabria
THIS DOCUMENT RELATES TO: ALL ACTIONS	
SURGICAL INSTRUMENT SERVICE COMPANY, INC., Plaintiff and Counter-defendant, vs. INTUITIVE SURGICAL, INC., Defendant and Counterclaimant.	Case No. 3:21-cv-03496-VC Hearing Date: June 8, 2023 Hearing Time: 1:00 PM Hearing Place: Courtroom 4 Judge: Hon. Vince Chhabria

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NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on June 8, 2023, at 1:00 PM, or as soon thereafter as available, in the courtroom of the Honorable Vince G. Chhabria, located at 450 Golden Gate Avenue, Courtroom 4, 17th Floor, San Francisco, CA 94102, Defendant/Counterclaimant Intuitive Surgical, Inc. will and hereby does move for an order in both of the above-captioned cases excluding certain testimony of Dr. T. Kim Parnell.

This Motion is based on this Notice of Motion, the Memorandum of Points and Authorities, the accompanying Declaration of Isaac D. Chaput and attached exhibits, any reply or other supplemental briefing and/or evidence submitted, and the oral argument of counsel.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

One of the core issues in this litigation is whether Intuitive's challenged conduct – limiting the number of times its EndoWrist instruments can be used – is procompetitive because it is designed to promote patient safety by reducing the likelihood that EndoWrist instruments will fail during surgery. Both SIS and the hospital plaintiffs have retained Dr. T. Kim Parnell, an engineer who offers several opinions purporting to bear on this subject. Most of those opinions are inadmissible under Rule 702.[1]

Dr. Parnell is a mechanical engineer, not a surgeon. Yet his reports substantially overreach, relying on assertions about surgical methods, patient safety, and standard practices in the health-care industry, subjects on which he has no expertise. Even when offering opinions within his field of expertise, he often relies on speculation rather than the kind of hard data or technical analysis that a true expert in this field would be expected to focus on. In the *Rebotix* litigation involving substantially

[1] Dr. Parnell offers substantially identical opinions in his reports in the two cases. To promote judicial economy, Intuitive accordingly is filing this motion in both cases instead of burdening the Court with two largely identical motions.

similar issues, several of Dr. Parnell's opinions were excluded.[2] Those opinions should be excluded here as well, along with additional opinions he offers here that similarly fail the basic *Daubert* test.

First, Dr. Parnell opines that the EndoWrist use counter is an "inadequate" method of ensuring patient safety. As the *Rebotix* court held, Dr. Parnell lacks the expertise necessary to support opinions about patient safety. Moreover, although purporting to testify as a technical expert in a technical field, Dr. Parnell offers this opinion without reference to reams of hard technical data that were readily available to him, relying instead on a series of unsupported assumptions about how these instruments are used in, and affected by, surgery – a subject on which his knowledge consists of nothing more than watching a handful of surgery videos. This kind of result-oriented, science-ignoring opinion is exactly the kind of testimony that fails the *Daubert* test.

Second**,** repeating and expanding upon a related opinion also excluded in *Rebotix*, Dr. Parnell speculates that the EndoWrist use counter could be redesigned to limit usage based, not on the number of surgical procedures for which an instrument is used, but rather through a hypothetical algorithm based on surgical use time and the forces applied. But he does not claim such a design exists; nor does he offer one. Indeed, he does not even attempt to explain how such a design would be possible as a matter of engineering, let alone practical for use in real life.

Third, in a transparent effort to discount real-world evidence that EndoWrists whose use counters are expired are indeed at the end of their useful lives, Dr. Parnell asserts that certain EndoWrists he observed at a Rebotix Repair LLC ("Rebotix") facility in August of 2021 were broken due to "damage from an external object or misuse," rather than normal wear-and-tear. But he offers no methodology to support that opinion, which he admits rests on nothing more than a "limited inspection" of instruments selected by Rebotix for his review.

Fourth, Dr. Parnell opines that EndoWrists may be repaired like laparoscopic instruments. But this opinion, again, depends on assertions that he is simply not qualified to make. Dr. Parnell has almost

[2] *See* Chaput Dec. Ex. 5 (*Rebotix Repair LLC v. Intuitive Surgical, Inc.*, 8:20-cv-2274, Order on Intuitive's Motion to Exclude (Aug. 10, 2022), ECF No. 183).

no experience with laparoscopic instruments and admits that he has not actually compared them to EndoWrists. Dr. Parnell's attempt to offer a similar opinion in the *Rebotix* matter was rejected.

Fifth, Dr. Parnell opines that, although SIS did no safety testing, it acted "reasonably" in marketing a service to modify EndoWrists to reset their use counters as safe and effective by relying on a single summary document sent by Rebotix. This opinion is not based on any relevant expertise or on any reliable expert methodology.

The Court should exercise its function as "gatekeeper" for expert testimony to exclude Dr. Parnell's proposed testimony concerning these opinions.[3]

II. FACTUAL BACKGROUND

Dr. Parnell is a mechanical engineer. Chaput Dec. Ex. 1 (Parnell *Larkin* March 1, 2023 Report) ¶ 1.[4] In his reports in these cases, he opines that the EndoWrist use counter is "inadequate" to protect patient safety because it "does not measure actual wear experienced by instruments in surgeries." *Id.* § X.A. He speculates that the EndoWrist use counter could be redesigned to measure and limit usage based on some combination of surgical use time and forces applied, but he does not attempt to explain what this design would consist of or how it would be accomplished. *Id.* ¶ 230.

Dr. Parnell also discusses a trip he made to Rebotix's facility in August 2021, where he saw a number of broken EndoWrists. He asserts that none of those instruments were damaged "due to wear," but instead had suffered "damage from an external object or from misuse." *Id.* ¶ 91. He does not explain how he arrived at that determination.

[3] For the avoidance of doubt, Intuitive reserves the right to raise additional objections to Dr. Parnell's testimony at a later date. For example, during his deposition Dr. Parnell suggested he may "offer opinions at trial in this case based on material that is in [his] *Rebotix* report" but not in his reports in this litigation. Chaput Dec. Ex. 6 (Parnell Dep.) 232:7–233:4. In the event Dr. Parnell attempts to offer such an opinion, Intuitive expects to object at that time. *See* Fed R. Civ. P. 26(a)(2)(B)(i); *see also id.* 37(c)(1).

[4] Dr. Parnell's March 3, 2023 report in the hospital case largely repeats the opinions set out in his two *SIS* reports. Unless otherwise stated, citations herein are to his report for the hospitals ("Larkin"), but the same opinions are offered in his *SIS* reports.

Dr. Parnell also opines that it is "standard practice" for hospitals to repair their laparoscopic instruments, including "wear" on laparoscopic instrument cables, and that EndoWrists can be "repaired" in just the same way. *Id.* ¶ 35. At deposition, however, he admitted that he is not aware of any commercially-available laparoscopic instrument that even has cables, let alone cables that can be "repaired." Chaput Dec. Ex. 6 (Parnell Dep., March 10, 2023) at 101:9–19.

Finally, Dr. Parnell opines that SIS acted "properly" in performing no safety testing, because its personnel "relied on the testing of their trusted technology partner, Rebotix, regarding the EndoWrist repair process." *Id.* ¶ 102. He does not claim to be an expert in standard business or safety practices in the medical device industry.

Dr. Parnell was originally retained by Rebotix in that entity's litigation against Intuitive. *See* Chaput Dec. Ex. 4 (*Rebotix* Report) ¶ 17. In an order issued on August 10, 2022, the *Rebotix* court excluded several of Dr. Parnell's opinions under Rule 702. The *Rebotix* court largely excluded his opinion that the use counter does not promote patient safety, including his conclusory opinion on a hypothetical alternative design for the use counter, because "the Court fail[ed] to see how Dr. Parnell's training as a mechanical engineer makes him qualified to opine on patient safety." Chaput Dec. Ex. 5 at 11.[5] The court also excluded his opinion that EndoWrists can be routinely repaired like laparoscopic instruments, because, *inter alia*, Dr. Parnell had no experience with laparoscopic instruments. *Id.* at 15. Finally, the court excluded as a legal conclusion his opinion that "Intuitive has 'no basis' to make a claim about the safety or reliability of EndoWrists." *Id.* at 13.

Neither SIS nor the hospital plaintiffs disclosed Dr. Parnell in the opening round of expert disclosures, when parties were required to submit expert reports on issues on which they have the burden of proof; instead, SIS served a "rebuttal" report from him in the second round and a 120-page "reply" report in the final exchange. The hospital plaintiffs did not offer any opinions from Dr. Parnell

[5] The *Rebotix* court authorized Dr. Parnell to provide his technical assessment of Intuitive's failure-mode testing, because that aspect of his opinion was "based on his experience as a mechanical engineer." *Id.* at 12. That aspect of Dr. Parnell's opinions is not a subject of this motion.

until the final round of "reply" reports.[6] Across his three reports, he offers all but one of the same opinions he offered in *Rebotix*, including those that were excluded.[7] To those, he has added his opinion about the reasonableness of SIS's conduct in relying upon representations from Rebotix. Dr. Parnell acknowledged at deposition that while he considered the *Rebotix* order when drafting his reports in this litigation, he has not materially altered his opinions. Chaput Dec. Ex. 6 at 31:25–32:17.

III. ARGUMENT

Expert witness testimony must (1) come from a qualified expert; (2) be helpful to the factfinder; (3) be based on sufficient facts or data; (4) use reliable principles and methods; and (5) reliably apply those principles and methods to the facts of the case. Fed. R. Evid. 702. The Court's "gatekeeping" role requires evaluating both the reliability of the expert's methods and the connection between their conclusions and the facts on which those conclusions are based. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 143–46 (1997). These requirements go to admissibility, not weight, and the proffering party has the burden of satisfying them. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 n. 10 (1993); *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 283–85 (4th Cir. 2021) (discussing forthcoming amendments to Rule 702).

A. The *Rebotix* Court Was Correct in Excluding Dr. Parnell's Opinions About the Adequacy of the Use Counter to Protect Patient Safety.

Dr. Parnell opines that the EndoWrist use counter is "inadequate" because it "does not measure actual wear experienced by instruments in surgeries," "does not take into account mishandling or misuse," and "fails to independently verify the condition of the instrument [because] [h]ospital

[6] Insofar as he is permitted to testify in either case, therefore, he may only testify in plaintiffs' rebuttal cases, and not their cases-in-chief. "Rebuttal testimony cannot be used to advance new arguments or new evidence." *Huawei Techs., Co, Ltd v. Samsung Elecs. Co, Ltd.*, 340 F. Supp. 3d 934, 995 (N.D. Cal. 2018) (quotation omitted); *see also* Fed R. Civ. P. 26(a)(2)(B)(i), 37(c)(1).

[7] *Compare* Chaput Dec. Ex. 4 (*Rebotix* Report) at i–iii *with* Chaput Dec. Ex. 2 (March 1 *SIS* Report) at i–ii *and* Chaput Dec. Ex. 1 (*Larkin* Report) at i–v. Dr. Parnell has dropped his opinion that new EndoWrists are less safe than reset EndoWrists. *See* Chaput Dec. Ex. 4 (*Rebotix* Report) at § VII.

technicians must do an inspection to ensure that the instrument is safe." Chaput Dec. Ex. 1 §§ X.A, B, D. This opinion should be excluded for multiple reasons.

First, these opinions do not fit with the issues in this case. "Expert opinion testimony is relevant if the knowledge underlying it has a valid connection to the pertinent inquiry." *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010) (quoting *United States v. Sandoval-Mendoza*, 472 F.3d 645, 654 (9th Cir. 2006)). An opinion that does not "fit" the issue that a jury must decide is irrelevant and thus inadmissible. *See Daubert*, 509 U.S. at 591 ("Rule 702 further requires that the evidence or testimony 'assist the trier of fact to understand the evidence or to determine a fact in issue.' This condition goes primarily to relevance.").

Here, plaintiffs' claims do not rest on the proposition that the use limits for EndoWrists are insufficient to guarantee patient safety; rather, they rest on the proposition that the use limits are *too strict*. Dr. Parnell does not contend that it is unreasonable to treat EndoWrists as limited-use devices that will predictably fail, with resulting risk to patients. *See, e.g.*, Chaput Dec. Ex 1 ¶¶ 250–251. His main opinion here (discussed in the next section below) is rather that the goal of mitigating patient safety risk could, at least hypothetically, be achieved in a way that allows additional use of the devices through a usage counter that relied on *different* criteria. An assertion that the current design is less than perfect in protecting patient safety is a straw-man argument and not relevant to the issues the factfinder must decide.[8]

Second, Dr. Parnell's opinions about the "inadequacy" of the use counter depend on assumptions about surgical practices that are outside his qualifications. The gist of his opinion is that the use counter is inadequate because it fails to track the length or intensity of the instrument's use in individual surgeries. *See id.* ¶ 219. He also quotes medical studies that recite variations in surgical procedure times: "[o]ne study examining laparoscopic colon surgeries found ranges between 50 and 300 minutes

[8] Intuitive has never taken the position that the use limits are, standing alone, sufficient to guarantee patient safety. They are, rather, designed to *manage* risks associated with the wear and tear experienced by these relatively fragile instruments during multiple surgeries.

for Ileocecal colectomies, between 62 and 330 minutes for sigmoid colectomies, and between 130 and 590 minutes for total abdominal colectomies." *Id.* ¶ 218.

Dr. Parnell does not know what ileocecal, sigmoid, or total abdominal colectomies are, and he readily admits that he is not a medical doctor qualified to opine on matters related to them. Chaput Dec. Ex. 6 at 144:14–145:5. While Dr. Parnell has some experience evaluating completely different kinds of medical devices as an engineer, none of his academic or professional experience has involved EndoWrists – or anything like them. *See* Chaput Dec. Ex. 1 § I, Attach. A.; Chaput Dec. Ex. 6 at 68:21–71:6 (explaining experience with implantable devices such as stents and filters, fixation devices such as plates and screws, closure devices such as ligation clips). He has no real-life experience with evaluating the impact of procedure duration or other factors on the deterioration of EndoWrists. He has never even seen a da Vinci surgery performed in person, much less evaluated the EndoWrists used in that surgery to assess the impact of the duration of the surgery or the pressures used. He has observed a few da Vinci surgeries – but all by video. *See* Chaput Dec. Ex. 7 at 30:7–22; Chaput Dec. Ex. 6 at 73:9–74:14.

Courts routinely exclude expert testimony where the expert's opinion is not within the scope of his expertise. *See, e.g.*, *Avila v. Willits Envt'l Remediation Trust*, 633 F.3d 828, 839 (9th Cir. 2011). The *Rebotix* court excluded Dr. Parnell's opinion that the use counter did "not promote patient safety" for exactly that reason. Chaput Dec. Ex. 5 at 11–12; *see* Chaput Dec. Ex. [X] § VI. The court "fail[ed] to see how Dr. Parnell's training as a mechanical engineer makes him qualified to opine on patient safety. Most of the facts undergirding this opinion could just as easily be offered by surgeons or surgical technicians who work with the EndoWrists in the operating room . . . ." Chaput Dec. Ex. 5 at 11.[9]

Third, Dr. Parnell does not claim to have examined or tested *any* EndoWrists following a surgery, much less to perform a program of rigorous testing designed to generate statistically significant

[9] Although acknowledging that his opinions on this are the same in this case as in *Rebotix*, Chaput Dec. Ex. 6 at 31:25–32:17, Dr. Parnell made slight changes to the relevant sections of report in an apparent attempt to evade the *Rebotix* ruling, primarily to *delete* material that was most obviously beyond his expertise. However, the primary sections relating to this opinion remain otherwise essentially identical. *Compare* Chaput Dec. Ex. 1 § X.A–D *with* Chaput Dec. Ex. 4 (*Rebotix* Report) §§ VI.B, VI.A–E.

results that might support his conclusions about how wear-and-tear on an instrument can reliably be measured and predicted. At the same time, Dr. Parnell chooses to ignore critical data and other technical information bearing on that question.

Courts regularly exclude experts who reach their conclusions by selective use of data and studies, particularly when they choose to ignore the bulk of the data available. *See, e.g.*, *In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1176 (N.D. Cal. 2007) ("[The expert] reaches his opinion by first identifying his conclusion—causation at 200 mg/d—and then cherry-picking observational studies that support his conclusion and rejecting or ignoring the great weight of the evidence that contradicts his conclusion."); *see Claar v. Burlington N. R. Co.*, 29 F.3d 499, 503 (9th Cir. 1994) (experts "whose conviction about the ultimate conclusion of their research is so firm that they are willing to aver under oath that it is correct prior to performing the necessary validating tests could properly be viewed by the district court as lacking the objectivity that is the hallmark of the scientific method").[10]

Here, Dr. Parnell criticizes the use counter as arbitrary, while completely ignoring the extensive risk management process and life testing data underlying it. As Intuitive's engineering expert Dr. Howe explains in his report, "Intuitive employs rigorous and in-depth design control and risk management processes" which follow FDA guidelines. Chaput Dec. Ex. 8 (Howe (*Larkin*) Rebuttal) ¶¶ 52. Among other things, Intuitive's life testing subjects EndoWrists to simulated surgical uses and feeds the results through sophisticated statistical models. *Id.* ¶¶ 64–72. Data from this extensive testing was supplied to FDA and formed the basis for the use limits that were proposed to, and cleared by, federal regulators. Chaput Dec. Ex. 10 (Foreman (*Larkin*) Report, Jan. 18, 2023) ¶¶ 83, 87, 92, 96, 100.

[10] *See also In re Countrywide Fin. Corp. Mortg.-Backed Sec. Litig.*, 984 F. Supp. 2d 1021, 1039–40 (C.D. Cal. 2013) (excluding expert analysis that relied on an unrepresentative and plaintiff-favorable sample); *Cloud v. Pfizer Inc.*, 198 F. Supp. 2d 1118, 1135–36 (D. Ariz. 2001) (excluding opinion that ignored plaintiff's medical records and defendant's FDA submissions); *Barber v. United Airlines, Inc.*, 17 F. App'x 433, 437 (7th Cir. 2001) (affirming exclusion of expert who "did not adequately explain why he ignored certain facts and data"); *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices and Prods. Liab. Litig.*, 145 F. Supp. 3d 573, 575 (D.S.C. 2015) (excluding "results driven" expert opinion where the expert's "methodology and selection of relevant evidence changed based on the results they produced"), *aff'd* 892 F.3d 624, 635 (4th Cir. 2018).

Yet, perhaps because this data contradicts his opinions, Dr. Parnell chose to ignore it. He simply dismisses Intuitive's life testing in general because Intuitive did not always test "to failure," relying on a selective reading of Intuitive deposition testimony rather than addressing the entirety of the testing record on the merits. Chaput Dec. Ex. 1 at ¶¶ 250–261. If plaintiffs wish to offer his critique of Intuitive's testing protocols at trial, they are free to do so; the flaws in that critique are numerous but can be readily addressed on cross-examination. But he cannot go further and offer conclusory contrary opinions on these technical issues based on no data at all.

B. Dr. Parnell's Opinions Regarding an Alternative Use Counter Design Are Pure Unsupported Speculation.

Taking the next step following his opinion that the existing use counter design is "inadequate," Dr. Parnell goes on to suggest that Intuitive could redesign EndoWrists to measure and limit use according to different criteria.[11] Specifically, he suggests that the use counter could somehow be redesigned to control usage based on each individual instrument's use time and the forces applied to the instrument in the procedures in which it was used. *Id.* ¶ 230. This sweeping assertion should be excluded because it rests on little more than his say-so.

Dr. Parnell offers his suggested use counter redesign without any factual basis or reliable analysis. His only *factual* support is a few pages of deposition testimony in this litigation from one Intuitive employee discussing certain data that is tracked by da Vinci Systems; he infers from this that at least some data necessary for such a redesign might be available in the system. *See id.* (citing Chaput Dec. Ex. 11 (Duque 30(b)(6) Dep.) 13:22–15:15, 16:6–17:14, 18:25–19:10). But there is nothing in that testimony – or in anything else that Dr. Parnell cites – to support a conclusion that it would be a simple matter – or even possible – to create and implement the fundamental design change that he hypothesizes.

Product design is a function of a complex series of engineering, financial, economic, marketing, logistical, and business considerations. Indeed, Dr. Parnell admitted that "design of anything, medical

[11] This opinion is, again, largely the same as the one excluded in *Rebotix*, although here he seeks to bolster it with additional deposition testimony taken in this litigation. As discussed below, that testimony does not salvage this opinion.

devices like any other device, [has] a lot of considerations," including at minimum: customer needs, Chaput Ex. 6 at 53:20–54:9; the degree of sophistication of the user or amount of training required, *id.* at 54:20–23; choice of materials used in the product, *id.* at 54:24–56:11; and product performance, cost, and manufacturability, *id.* at 56:12–20. Dr. Parnell's report makes no mention of these factors, let alone any analysis of them or a concrete alternative design that takes them into account. And he admits having made no effort to do so. *Id.* at 151:16–23, 153:20–154:5.

Where it is "unclear what methods or principles [the expert] is applying to the facts of the case," "it is impossible to say that [the expert's] testimony is reliable." *Al-Daiwa, Ltd. v. Apparent, Inc.*, 2015 WL 5304111, at *1 (N.D. Cal. Sept. 9, 2015) (Chhabria, J.); *see also Aya Healthcare Servs., Inc. v. AMN Healthcare, Inc.*, 2020 WL 2553181, at *4 ("[Expert] '[k]nowledge' requires more than a subjective belief or an unsupported speculation . . . ." (citing *Daubert*, 509 U.S. at 593)). Dr. Parnell's opinion that an alternative design is feasible is pure *ipse dixit* speculation supported by no expert methodology.

For the foregoing reasons, the Court should exclude Dr. Parnell's speculative opinion that an alternative design of the EndoWrist use counter is hypothetically possible.

C. Dr. Parnell's Opinion on the Cause of Failure of EndoWrists He Observed Is Speculative and Unreliable.

During a visit to Rebotix's facility in August 2021, Dr. Parnell observed several EndoWrists that Rebotix had deemed "Unsuitable for Repair" because they were damaged, most due to broken drive cables. Chaput Dec. Ex. 1 ¶ 23, ¶¶ 86–92. Deterioration of drive cables after multiple uses is one of the primary modes of failure that the EndoWrist use limits are designed to address. Chaput Dec. Ex. 8 ¶¶ 39–43, 67–72. But in an obvious effort to discount the significance of the real-world evidence he saw of this, Dr. Parnell opines that none of the instruments he saw were damaged "due to wear," but instead that all cable breaks were due to "damage from an external object or from misuse." Chaput Dec. Ex. 1 ¶ 91. In other words, Dr. Parnell is opining that, due to an amazing coincidence, every single EndoWrist Rebotix had in its possession with broken or damaged cables had been struck with a heavy object or

otherwise misused. Notably, he does not claim to have any knowledge of the actual history of *any* of those instruments. This opinion should be excluded, as it rests on no discernible methodology or analysis. *Joiner*, 522 U.S. at 146.

Dr. Parnell does not explain in his report (1) how he (or Rebotix) selected the broken instruments he examined, (2) whether he examined *all* EndoWrists rejected as unsuitable, (3) how he examined those broken instruments for damage (for example, whether he opened up the housing to examine the internal cabling or just glanced at the outside of the instrument), or (4) what evidence would indicate damage due to wear as opposed to an "external object or misuse." In his report, Dr. Parnell does provide photographs he took of two of the damaged instruments, Chaput Dec. Ex. 1 ¶¶ 88, 90, but he does not identify any physical features of the instruments represented in the photographs that constitute objective evidence of misuse or damage due to an "external object." Instead, Dr. Parnell concludes without explanation that because only one cable in the two photographed instruments broke (rather than all cables at once), it must mean that none of the cables wore out from surgical use. *See id.* ¶ 91. He does not explain why that would necessarily be so, however. For the remaining broken EndoWrists he offers nothing more than the conclusory statement that "[o]ther instruments with cables that I examined similarly reflected external damage and breakage, rather than normal wear." *Id.* The only thing connecting Dr. Parnell's conclusion to the EndoWrists he examined is "the *ipse dixit* of the expert." *Joiner*, 522 U.S. at 146.

During his deposition, Dr. Parnell admitted that he did not actually examine all the broken instruments; a Rebotix employee selected the ones he examined, possibly (though he could not remember) following instructions to identify instruments exemplifying certain types of failures. Chaput Dec. Ex. 6 at 163:19–166:12. Finally, when asked to explain the methodology he used in determining that the instruments he saw failed due to misuse rather than wear, he essentially admitted that the conclusion he had offered was speculative at best:

> [M]y conclusion is that it was possibly that way [due to external misuse rather than wear], maybe even likely that way. I can't say that it is absolutely 100,000 percent -- 100 percent that way. But it was my belief -

> - my experience in looking at that, that it looked like it appeared that one cable -- in those circumstances, one cable had gotten damaged in some mechanism, some external damage mechanism and the others, by virtue of being -- still appearing intact, still appearing to go through the pulleys properly, maybe still even operating the -- you know, their degree of freedom properly, that they were not associated with wear. That was my conclusion on a limited inspection though.

Id. at 176:6–19. In short, two years ago Dr. Parnell looked at a handful of selectively chosen EndoWrists and concluded that *all* failed due to external misuse, based on a "limited inspection" and how they "appeared" to him. This is not a reliable expert opinion, and the Court should exclude it.

D. Dr. Parnell's Opinion that EndoWrists Can Be Routinely Repaired in the Same Manner as Traditional Laparoscopic Instruments Is Irrelevant and Lacks a Reliable Basis.

Dr. Parnell opines that "traditional laparoscopic instruments are routinely repaired [and that] EndoWrists can be similarly repaired." Chaput Dec. Ex. 1 § V. This opinion should be excluded on multiple grounds.

First, this opinion, standing alone, is not relevant and would not assist the trier of fact. *See Daubert*, 509 U.S. at 591; *Primiano*, 598 F.3d at 565. This case is not about "repair" of broken EndoWrists; it is about modification of EndoWrists to prevent them from functioning exactly as they were designed so that they can be operated for more than the limited number of uses for which Intuitive designed them and FDA cleared them. An assertion that an EndoWrist that is genuinely broken can be "repaired" is a red herring. Dr. Parnell himself emphasizes that Rebotix screened EndoWrists being considered for its reset modifications and excluded those that were broken. Chaput Dec. Ex. 6 at 114:22–115:12. Repairing broken instruments was not what SIS was seeking to do or what the hospital plaintiffs are claiming to want. And since laparoscopic instruments do not have use counters, this comparison is a total non sequitur. Chaput Dec. Ex. 1 ¶ 231.

Second, Dr. Parnell is not qualified to offer this opinion because it relies on assertions about hospital and surgical practices and patient safety that he is not qualified to offer. He states, for example, that "[i]t is a standard practice of hospitals to repair instruments used in traditional laparoscopic surgeries," and "[EndoWrist] failures are easily recognized by surgeons, and surgeons regularly and

easily replace instruments when they exhibit unintuitive motion during surgery." *Id.* ¶¶ 35, 53. Reflecting his lack of personal experience with these matters, the portions of his report discussing them simply parrot testimony and documents of others. *See id.* ¶¶ 32, 34–35, 41–44, 53. For example, in asserting that "[h]ospitals . . . inspect EndoWrist instruments prior to surgery" and "failure modes on EndoWrists, just like on traditional laparoscopic instruments, are obvious," his report block quotes two pages of deposition testimony from a hospital employee. *Id.* ¶¶ 42–43 (quoting Harrich *Restore* Depo Tr. 40:9–42:4). If and to the extent any of this testimony is relevant (and is itself supported by adequate foundation), plaintiffs can offer it at trial; they cannot bolster it by having an expert with no special knowledge of the subject simply repeat it. Dr. Parnell may not "function[ ] as a mouthpiece of the individuals on whose statements . . . he purports to base his opinion." *Caldwell v. City of San Francisco*, 2021 WL 1391464, at *5 (N.D. Cal. Apr. 13, 2021) (collecting cases) (quotations omitted).

Third, Dr. Parnell's opinion comparing EndoWrists to laparoscopic instruments is unreliable because he has no expertise with laparoscopic instruments, as is made clear by his report and deposition. Dr. Parnell opined in his report that "[l]aparoscopic instruments in need of repair can suffer from . . . worn or damaged cables" – a "failure mode" he says is "common." Chaput Dec. Ex. 1 ¶ 38. But during his deposition, Dr. Parnell admitted that he is not aware of *any* commercially available traditional laparoscopic instrument that even has cables. Chaput Dec. Ex. 6 at 101:9–19.[12] This testimony makes clear that Dr. Parnell's opinions cannot possibly be based on his own expertise, since he is opining on a "common" failure mode for a component he is not even certain exists. In *Rebotix*, Dr. Parnell's purported comparison of EndoWrists and laparoscopic instruments was excluded because he "admitted that he had no experience with laparoscopic instruments prior to this litigation, and he did not examine any laparoscopic instruments in connection with this case." Chaput Dec. Ex. 5 at 15; Chaput Dec. 7 at 18:25–21:6, 47:15–24. In an effort to address this, he now claims to remember that he *may* have "had the opportunity to see instruments previously like in my visits to Stanford, visits with doctors at

[12] SIS itself admitted, in testimony Dr. Parnell ignores, that traditional laparoscopic instruments do not have similar cables to EndoWrist instruments. Chaput Dec. Ex. 12 (Johnson 30(b)(6) Dep.) at 27:15–20).

Stanford," which was enough for him to "fe[el] like [he] was familiar with those devices." Chaput Dec. Ex. 6 at 86:4–87:8. And after his *Rebotix* deposition he claims to have "watched portions of [laparoscopic] procedures." *Id.* at 71:8–17. None of this could possibly have given Dr. Parnell a basis to compare EndoWrists and laparoscopic instruments with the "same level of intellectual rigor" as would be applied by an engineer comparing medical devices in the field. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999).

E. Dr. Parnell's Opinions Regarding the "Reasonableness" of SIS's Decision to Rely Entirely on Safety Representations Made by Rebotix Are Not Proper Expert Testimony.

Dr. Parnell opines that "SIS properly relied on the testing of [its] trusted technology partner, Rebotix, regarding the EndoWrist repair process." Chaput Dec. Ex. 1 § VII ¶¶ 102. He cites as support SIS's "long-standing relationship with the principals of Rebotix spanning at least 20 years." Chaput Dec. Ex. 2 (March 1 *SIS* Report) ¶ 91. Dr. Parnell further opines that "it would not make sense for Rebotix to provide SIS with the technical details of its testing or repair procedures," because doing so "would result in the possible loss of valuable intellectual property rights." *Id.* ¶ 93. The purpose of this opinion is to justify SIS's failure to perform any independent safety analysis of its own. The Court should exclude this opinion because it is based on no reliable *expert* methodology or experience.

Dr. Parnell does not identify any relevant experience he can draw on to evaluate standard *business* practices for evaluating and managing safety issues in the medical device repair industry. Instead, he simply parrots the deposition testimony of SIS employees and things he was told by Greg Posdal, President and CEO of SIS. Expert opinions cannot rest on unverified assertions from the parties who hired them. *Mission Viejo Florist, Inc. v. Orchard Supply Co., LLC*, 2019 WL 13045054, at *4 (C.D. Cal. Feb. 28, 2019) (rejecting expert damages calculation that "relied solely" on an "unverified estimate" from the plaintiff); *see also Al-Daiwa*, 2015 WL 5304111, at *1 (excluding Defendant expert's testimony where the witness's report "consist[ed] mostly of a rehashing of [Defendant's] version of events, of statements for which there is no reason an expert would be needed, and of broad conclusions about how [Defendant] followed generally-accepted business practices").

Finally, Dr. Parnell attempts to justify these opinions by asserting that Rebotix's representations to SIS regarding its service processes were "truthful." Chaput Dec. Ex. [X] ¶ 95; *see also id.* ¶ 93. This opinion is not only beyond the scope of Dr. Parnell's expertise, but it is an impermissible attempt to bolster Rebotix's and SIS's credibility – an issue reserved for the jury. *See, e.g.*, *United States v. Candoli*, 870 F.2d 496, 506 (9th Cir. 1989).

For these reasons, the Court should exclude Dr. Parnell's opinion that SIS "properly" or "reasonably" relied on Rebotix's representations regarding the EndoWrist reset process.

IV. CONCLUSION

For the reasons set forth above, the Court should exclude Dr. Parnell's opinions that:

(1) the EndoWrist use counter is an "inadequate" method of ensuring patient safety;

(2) the EndoWrist use counter could be re-designed in the manner Dr. Parnell hypothesizes;

(3) broken EndoWrists he observed at Rebotix all failed due to "damage from an external object or misuse" rather than wear-and-tear;

(4) EndoWrists can be routinely repaired like traditional laparoscopic instruments; and

(5) SIS acted "reasonably" in performing no safety evaluation and instead relying entirely on Rebotix's representations.

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